

proper mixing order so that a composition alteration or an incompatibility between a plurality of injections will not occur for the patient. Therefore, the apparatus of the present invention decides a proper mixing order of a plurality of injections so that the plurality of injections can be properly combined before the patient is infused with the injections.

Claim 19

Claim 19 recites the above-described features of the present invention. In particular, claim 19 recites an apparatus for supporting injection mixing work. The apparatus of claim 19 is defined as comprising (1) an acquisition unit operable to acquire an injection prescription data including data specifying a plurality of injections which are prescribed to a patient.

The apparatus of claim 19 is also defined as comprising (2) a decision unit operable to decide a proper mixing order of the plurality of injections included in the prescription data acquired by the acquisition unit.

Furthermore, the apparatus of claim 19 is defined as comprising (3) a display unit operable to display an indication representing the mixing order decided by the decision unit.

Claim 19 also defines that (4) the decided mixing order displayed by the display unit is used to properly combine a plurality of the injections which are prescribed to the patient.

In item 4 on page 2 of the Office Action, the Examiner opined that Teeple discloses the above elements (1)-(4) of claim 19 in Column 3, lines 42-60 of Teeple. As demonstrated below, Teeple does not disclose or suggest any of elements (1)-(4) of claim 19.

Column 3, lines 42-60 of Teeple provide the following disclosure:

The present invention may also use an apparatus for determining and/or preparing a drug solution for continuous infusion, which may include:

1. a means for inputting data;
2. a memory means for storing data, the memory means having stored therein a predetermined dosage rate for the drug and a standardized rate of infusion;
3. a means operable to determine a required concentration of the drug on the basis of the predetermined dosage rate, the standardized rate of infusion and a patient weight supplied via the input means; and

4. a means for displaying the required concentration and/or preparing the final mixed bag of drugs and dilute to be administered.
5. a means for mixing diluent and drug concentrate(s) into a final mixed bag ready for administration.
6. a means for marking the constituents on the outside of each final mixed bag.

Accordingly, Teeple merely discloses an apparatus and method for determining a required concentration of a drug, and displaying the determined required concentration of the drug. However, as will be further demonstrated below, Teeple does not disclose or suggest deciding a proper mixing order of a plurality of injections which are prescribed to a patient.

Element (1) of Claim 19

The Examiner alleges that (1) an acquisition unit operable to acquire an injection prescription data including data specifying a plurality of injections which are prescribed to a patient is disclosed in Column 3, lines 42-46 of Teeple, which corresponds to the means number 1 above.

However, Column 3, lines 42-46 of Teeple merely disclose a means for inputting data corresponding to a patient's weight by an operator. That is, an operator's act of inputting data does not amount to acquiring injection prescription data specifying a plurality of injections which are prescribed to a patient, as recited in claim 19. Accordingly, Teeple clearly does not disclose or suggest the acquisition unit of claim 19.

Element (2) of Claim 19

The Examiner alleges that (2) a decision unit operable to decide a proper mixing order of the plurality of injections included in the acquired injection prescription data is disclosed in Column 3, lines 50-53 of Teeple, which corresponds to the means number 3 above.

However, Column 3, lines 50-53 of Teeple merely disclose a means operable to determine a required concentration of a drug based on a predetermined dosage rate and a standardized rate of infusion, which are stored in a memory (means number 2 above), as well as a patient weight which is inputted into the input means (means number 1 above).

Accordingly, Teeple merely discloses determining a required concentration of a drug to be infused to a patient so that a clinical physician is not required to constantly monitor the infusion of a drug to ensure that the proper dosage is given to the patient.

However, determining a required concentration of a drug is markedly different in both purpose and effect from deciding a proper mixing order of a plurality of injections which are prescribed to a patient. Accordingly, despite the Examiner's assertion to the contrary, the Applicants respectfully submit that Teeple clearly does not disclose or suggest the decision unit of claim 19.

Element (3) of Claim 19

The Examiner alleges that (3) a display unit operable to display an indication representing the proper mixing order decided by the decision unit is disclosed in Column 3, lines 54-56 of Teeple, which corresponds to the means number 4 above.

However, the fourth means of Teeple is disclosed as displaying a required concentration, which is markedly different from displaying an indication representing the decided proper mixing order of the plurality of injections which are prescribed to a patient, as recited in claim 19.

Therefore, the Applicants respectfully submit that Teeple also clearly does not disclose or suggest the display unit of claim 19.

Element (4) of Claim 19

The Examiner also alleges that the decided mixing order which is displayed by the display unit is used to properly combine a plurality of the injections which are prescribed to the patient is disclosed in Column 3, lines 54-58 of Teeple, which corresponds to the means numbers 4 and 5 above.

However, Teeple merely discloses a means for preparing a final mixing bag of drugs and dilute to be administered, but does not disclose or suggest properly combining a plurality of drugs by using a decided proper mixing order of the drugs, as recited in claim 19.

Therefore, the Applicants respectfully submit that Teeple clearly does not disclose or suggest that the decided mixing order which is displayed by the display unit is used to

properly combine a plurality of the injections which are prescribed to the patient, as recited in claim 19.

For at least the foregoing reasons, the Applicants respectfully submit that claim 19 is clearly not anticipated by Teeple since Teeple fails to disclose each and every limitation of claim 19.

Furthermore, in view of the clear distinctions discussed above, the Applicants respectfully submit that it would not have been obvious to modify the method and apparatus of Teeple for determining a required concentration of a drug in order to result in, or otherwise render obvious, the invention of claim 19.

Therefore, the Applicants respectfully submit that claim 19 is clearly patentable over Teeple.

Claims 20-32 and 34

Claims 20-32 and 34 depend from claim 19. As demonstrated above, Teeple does not disclose or suggest each and every limitation of claim 19. Therefore, Teeple cannot be interpreted as disclosing or suggesting the limitations recited in claims 20-32 and 34 since Teeple does not disclose or suggest each and every limitation of claim 19.

Claim 33

In item 20 on page 6 of the Office Action, claim 33 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Teeple, Jr. in view of Merki et al. (U.S. 5,002,055, hereinafter “Merki”).

As demonstrated above, Teeple clearly fails to disclose or suggest elements (1)-(4) of claim 19. Similarly, Merki also fails to disclose or suggest these elements of claim 19. Therefore, no obvious combination of Teeple and Merki would result in the invention of claim 19 since Teeple and Merki, either individually or in combination, fail to disclose or suggest each and every limitation of claim 19.

Accordingly, Teeple and Merki also cannot render obvious the invention of claim 33 since claim 33 depends from claim 19.

Nevertheless, the Applicants are compelled to establish that Merki does not disclose or suggest determining a proper mixing order of a plurality of injections which

are prescribed to a patient based on pH-value data of the injections, as recited in claim 33, since this fact has already been established in previous responses of the Applicants.

While acknowledging that Teeple does not disclose or suggest deciding a proper mixing order of a plurality of injections which are prescribed to a patient based on pH-values, the Examiner alleges that such a feature is disclosed in Merki. In support of this assertion, the Examiner refers to Column 3, lines 52-63 of Merki, which are reproduced below:

The pH-sensor 1 intraluminally measures the H^+ -ion activity. The measured data are stored and compared with the reference values stored in the microprocessor. For setting the therapy objective, e.g., raising the pH-value, microprocessor 12 activates the first pump for the administration with standard drugs, e.g., H_2 -antagonist or ATP-ase inhibitors, either as a primed infusion, i.e., a bolus, followed by a continuous infusion or an intermittent infusion. The standard doses administered by the pump are increased or decreased stepwise by comparing the therapy objective with the patient's response.

This portion of Merki, or any other portion of Merki for that matter, does not disclose or suggest that determining a proper mixing order of a plurality of injections which are prescribed to a patient is determined based on pH-value data of the injections.

Instead, as clearly understood from the above referenced portion, Merki discloses an apparatus for the biofeedback control of body functions, e.g., gastric-pH control in which the pH-sensor 1 intraluminally measures the H^+ -ion activity and the microprocessor 12 activates a pump for administration with a standard drug based on the measured data to, for example, raise the pH-value.

In other words, Merki merely discloses that the pH sensor 1 intraluminally measures the H^+ -ion activity of gastric juices, and that the measured pH data resulting from the infusion of a primary medication are stored and compared with the reference values that are stored in a microprocessor.

Merki also discloses that, during the infusion of a prescribed medication, another medication can be combined with the prescribed medication when the measured pH values are deemed to be unacceptable so as to achieve the desired therapy objective.

This feature of Merki is merely a part of a therapy method including the selection of drugs and the regulation of administrative speed based on the patient's condition

during the infusion of a prescribed medication. However, Merki clearly does not disclose, suggest or even contemplate deciding a mixing order of a plurality of injections which are prescribed to a patient based on pH values data for each injection so that a plurality of the injections which are prescribed to the patient can be properly combined, as recited in claim 33.

Therefore, in addition to failing to disclose or suggest each and every limitation of claim 19, Teeple and Merki also clearly fail to disclose or suggest each and every limitation of claim 33.

Claims 35-37

In item 22 on page 6 of the Office Action, claims 35-37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Teeple, Jr. in view of Leissing et al. (U.S. 5,281,396, hereinafter “Leissing”).

Claim 35 depends from claim 19, and claims 36-37 each depend from claim 35. As demonstrated above, Teeple clearly fails to disclose or suggest elements (1)-(4) of claim 19. Similarly, Leissing also fails to disclose or suggest these elements of claim 19. Therefore, no obvious combination of Teeple and Leissing would result in the invention of claim 19 since Teeple and Leissing, either individually or in combination, fail to disclose or suggest each and every limitation of claim 19.

Nevertheless, the Applicants respectfully submit that Leissing does not cure the deficiencies of Teeple for failing to disclose each and every limitation of claim 35 for the following reasons.

Claim 35 recites that the apparatus of claim 19 further comprises an operation unit operable to operable to record a composition alteration, and a recorder operable to record the composition alteration.

With reference to Column 6, lines 10-23 and 60-68 of Leissing, the Examiner alleged that the invention of claim 35 is obvious in view of Teeple and Leissing. The Applicants respectfully traverse this rejection for the following reasons.

In column 6, lines 10-23, Leissing discloses an automated test system for evaluating the physical compatibility of a chemical in solution. In particular, Leissing discloses an automated, reproducible and quantitative measurement of any physical

aberration which results when two or more drugs come into contact with each other in a solution. In column 6, lines 60-68, Leissing discloses databases including tests of all two-drug combinations.

However, Leissing evaluates the physical compability of chemicals, which is markedly different from deciding and displaying a proper mixing order of a plurality of injections which are prescribed to a patient so that a plurality of the injections can be properly combined, as recited in claim 19, to prevent the improper mixing of drugs.

Moreover, the above-cited portions of Leissing do not disclose or suggest an operation unit operable to record a composition alteration, and a recorder operable to record the composition alteration, as recited in claim 35.

Therefore, in addition to failing to disclose or suggest each and every limitation of claim 19, Teeple and Leissing, either individually or in combination, clearly fail to disclose or suggest each and every limitation of claim 35. Teeple and Leissing also fail to disclose or suggest each and every limitation of claims 36 and 37 merely by virtue of failing to disclose or suggest the limitations of claim 35, from which claims 36 and 37 depend.

Because of the clear distinctions discussed above, it is submitted that the teachings of Teeple, Merki and Leissing clearly do not meet each and every limitation of claims 19, 33 and 35.

Furthermore, it is submitted that the distinctions are such that a person having ordinary skill in the art at the time the invention was made would not have been motivated to modify Teeple, Merki and Leissing in such as manner as to result in, or otherwise render obvious, the present invention as recited in claims 19, 33 and 35.

Therefore, it is submitted that the claim 19, as well as claims 20-37 which depend therefrom, are clearly allowable over the prior art as applied by the Examiner.

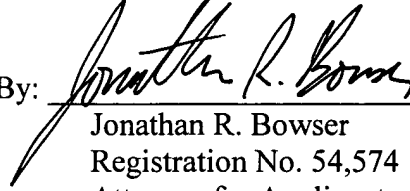
In view of the foregoing remarks, it is respectfully submitted that the present application is clearly in condition for allowance. An early notice thereof is respectfully solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the

Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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